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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Docket: LP-2012

Applicant : Hans-Peter METTLER
Serial No. : 10/569,824
Filed : February 28, 2006
Title : PROCESS FOR THE ASYMMETRIC HYDROGENATION
OF BETA-AMINO KETONES

COVER LETTER

Mail Stop Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

A copy of the Notice of Transmittal Of The International Preliminary Report
On Patentability is enclosed.

Respectfully submitted,

Date: May 8, 2006

Virgil H. Marsh
Reg. No. 23,083

Fisher, Christen & Sabol
1725 K Street, NW
Suite 1108
Washington, D.C. 20006
Tel.: 202-659-2000
Fax: 202-659-2015

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

LONZA AG
Münchensteinerstrasse 38
CH-4052 Basel
SUISSE

EINGEGANGEN

27. April 2006

Erl. BGK

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(PCT Rule 71.1)

Date of mailing
(day/month/year)

25.04.2006

Applicant's or agent's file reference
LP2012PC00

IMPORTANT NOTIFICATION

International application No.
PCT/EP2004/009690

International filing date (day/month/year)
31.08.2004

Priority date (day/month/year)
01.09.2003

Applicant
LONZA AG et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international
preliminary examining authority:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Morancho Alcaine, N

Tel. +49 89 2399-7462





PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference LP2012PC00	FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/EP2004/009690	International filing date (day/month/year) 31.08.2004	Priority date (day/month/year) 01.09.2003	
International Patent Classification (IPC) or national classification and IPC INV. C07D333/20 C07D307/52 C07D333/00			
Applicant LONZA AG et al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 26.03.2005		Date of completion of this report 25.04.2006	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer Steendijk, M Telephone No. +49 89 2399- 	

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2004/009690

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-12 as originally filed

Claims, Numbers

1-12 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 12

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 12

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-11
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-11
Industrial applicability (IA)	Yes: Claims	1-11
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/EP2004/009690

- 1) The present application relates to the preparation of chiral compounds of formula I by asymmetric hydrogenation of ketones of formula II in the presence of a transition metal complex with a chiral bidentate phosphine ligand (claims 1-11). Furthermore, certain compounds of formula I are claimed (claim 12). In view of a finding of non-unity, the following observations concern only the subject-matter of claims 1-11.
- 2) The following documents are referred to
D1: WO 03 062219 A
D2: WO 03 061825 A
D3: WO 03 061826 A
D4: ORGANIC LETTERS, vol. 2, no. 12, 2000, pages 1749-1751,
D5: CHEM, PHARM. BULL. vol. 43, no. 5, 1995, pages 748-753,
D6: WO 02 10113 A
- 3) Novelty
The claimed matter may be acknowledged novelty:
Document D1 describes a process for obtaining a compound of formula I by resolving the racemic compound.
Documents D2-D4 describe the asymmetric hydrogenation of ketones in the presence of a transition metal complex with a chiral bidentate phosphine ligand and a diamine; the ketones of formula II are not specifically mentioned.
Documents D5 and D6 describe the asymmetric hydrogenation of ketones in the presence of a transition metal complex with a chiral bidentate phosphine ligand; the ketones of formula II are not mentioned.
- 4) Inventive step
In view of Document D1 the problem to be solved may be seen in the provision of an alternative method for providing enantiomerically pure compounds of formula I. As solution to this problem the claimed matter would at present seem obvious to the person skilled in the art. Asymmetric synthesis is well established as alternative to resolving methods. The person skilled in the art would therefore consider application of successful approaches for asymmetric synthesis of structurally related compounds such as described in documents D2-D5, in which the asymmetric hydrogenation of

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

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related ketones in the presence of a transition metal complex with a chiral bidentate phosphine ligand with (D2-D4) or without (D5) diamines is described.